DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 5, 2014

Heraeus Medical GmbH
Dr. Astrid Marx
Junior Regulatory Affairs Manager
Philipp-Reis-Straße 8/13
61273 Wehrheim
Germany

Re: K142157
Trade/Device Name: PALACOS® R+G pro
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD, MBB, KIH, JDZ
Dated: July 25, 2014
Received: August 6, 2014

Dear Dr. Marx

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142157

Device Name
PALACOS® R+G pro

Indications for Use *(Describe)*

PALACOS® R+G pro is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Heraeus
Heraeus Medical GmbH

61273 Wehrheim, Germany

PALACOS® R+G pro

Radiopaque bone cement with gentamicin

Special 510(k) **510(k) Summary**

Date of summary	July 25th, 2014
Applicant's name and address	Heraeus Medical GmbH Philipp-Reis-Straße 8/13 61273 Wehrheim Germany
Device trade name	PALACOS® R+G pro
Common name	PMMA Bone Cement
Classification	PMMA Bone Cement : Class II special control per 21 CFR 888.3027 Cement Mixer for Clinical Use: Class I Exempt per 21 CFR 888.4210 Cement Dispenser: Class I Exempt per 21 CFR 888.4200
Classification name	Polymethylmethacrylate (PMMA) bone cement
Device code	LOD, MBB, KIH, JDZ
Identification of the marketed device to which equivalence is claimed	PALACOS® R+G, K031673
Reference device	SmartMix Cemvac Pre-filled with SmartSet GHV Gentamicin bone cement, K053445
Description of the device	PALACOS® R+G pro is an acrylic bone cement for use in orthopedic surgery. It is formed from powder and liquid by exothermic polymerization. It secures the fixation of the grafted artificial joint improving the transfer of forces at the interface implant - bone. The bone cement powder and liquid of PALACOS® R+G pro are pre-packed in a vacuum mixing and application system. This reduces the user steps and processing time during mixing of the bone cement. It also decreases the exposure to monomer fumes. PALACOS® R+G pro is available in one size: 75 g and is

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	for single use. The PALACOS® R+G pro device includes: • The mixing and application device pre-packed with the bone cement powder • One ampoule of monomer liquid pre-packed in a monomer cartridge • Accessories: a nozzle, a femur pressurizer, a vacuum sealed vacuum tube and in a separate box, an adaptor ring for the use with bone cement gun
Indications for use	PALACOS® R+G pro is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.
Comparison of technological characteristics	Bone cement is derived by mixing a powder component and a monomer liquid. The only difference between the subject and predicate device exists in a change to the primary packaging into a pre-packed application device to simplify the user handling of the components.
Discussion of nonclinical tests	The stability of liquid component, maximum temperature, setting time, intrusion, compressive strength, bending modulus and bending strength of PALACOS® R+G pro was characterized per ISO 5833. In addition, impact and bending strength were measured according to Dynstat test method. EtO sterilization was validated per ISO 11135. Biocompatibility testing, including cytotoxicity, irritation, sensitization, acute systemic toxicity, implantation, genotoxicity and chemical characterization was performed per ISO 10993.
Clinical performance data	No clinical data was provided.

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Special 510(k) **510(k) Summary**

Conclusions from nonclinical and clinical data	PALACOS® R+G pro is substantial equivalent to PALACOS® R+G.
Submitted by	Dr. Astrid Marx Phone: + 49 (0) 6181.35-2963 Fax: + 49 (0) 6181.35-2910 astrid.marx@heraeus.com
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